

**Remarks.**

Applicant thanks the Examiner for the courtesy of forwarding current claim pages. In accordance with the Examiner's request, reference has been made to the priority claim on Page 1 of the specification. The omission of the word "A" before "number" at line 23 on page 1 has been corrected. A substitute page 1 was filed previously.

Claim 1 has been amended by stating that the indicator has an anion. While this does not appear *ipsis verbis* in the specification, any one skilled in the art knows that a material having a cation must balance the charge with an anion. In any event, many anions are disclosed in the specification so that this amendment does not constitute new matter. Claim 9 has been amended by removing the duplicate of "styrene". Claims 42 and 45 have been amended to correct the spelling of "phosphorus". This amendment also meets the Examiner's criticism of claims 43, 45 and 40 as having no antecedent basis for "the anion".

Applicant respectfully traverses the rejection of claims 1-5, 9, 10, 40, 41, 43, 46 and 48 over Larson et al. The examiner states that Larson discloses the presence of monovalent cations. A close examination of this reference by the undersigned fails to reveal any statement with respect to monovalent cations or any specific cations. The cations disclosed are limited to bivalent cations, in particular magnesium, iron and zinc are also mentioned. Since there is no disclosure or even suggestion of monovalent cations, the basis of citation of Larson falls as grounds of anticipation under 35 USC 102(b)

The combination of Larson with Ignacio to ground a rejection of claims 6-8, 42, 44, and 47 under 35 USC 103 is not tenable either. Ignacio is a very limited reference to a method and device for monitoring liquid peracid and the vapors emanating from liquid peracid. Furthermore, the color change in Ignacio is due to a halogenation/dehydrohalogenation reaction, NOT pH change due to the peracid. There is no teaching of ethylene oxide as a sterilizing agent in Ignacio, neither is there any mention of peracid in Larson. Other than the fact that both are sterilizing agents, there is no incentive for one skilled in the art to consult either reference in view of the teaching of the other. In particular, since the magnesium of Larson is directed to ethylene oxide detection and the potassium of Ignacio is directed to peracid vapor detection from a liquid source or the liquid itself, there is no logical link for one skilled in the art to substitute the latter for the former, as the Examiner alleges.

Thus since the basis of combination of references to support an obviousness rejection requires suggestion of using a secondary reference to complete the teaching of a primary reference, and such suggestion is not present, the citation of these to references in combination is unsound and the rejection must be withdrawn.

In view of the foregoing, it would appear that there is no tenable ground for rejection of any of the claims in the present application, and their prompt passage to issue is respectfully solicited.

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This is to certify that the foregoing paper was transmitted by telefax to the Commissioner for Patents at 703 872 9306 on June 22<sup>nd</sup> 2004.

Respectfully submitted,



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**List of all claims showing changes made****In the Claims:**

Claims 1, 9, 42 and 45 have been amended:

- 1.(Currently Amended) A device for monitoring sterilization with ethylene oxide comprising:  
at least one layer of polymer, having incorporated therein
  - a) an indicator capable of undergoing at least one color change
  - b) an activator for said indicator, said activator having an anion and a monovalent cation, which, when contacted with ethylene oxide, undergoes a reaction wherein the product of said reaction causes said indicator to undergo said color change.
2. (Original) The device of claim 1 wherein the said indicator comprises at least one member of the group consisting of pigments, dyes, precursors of said dyes, and mixtures of any of the foregoing group members.
3. (Original) The device of claim 2 wherein the said indicator is a pH-sensitive dye.
4. (Original) The device of claim 3 wherein the said indicator is bromothymol blue, bromocresol purple, methyl red, ethyl red, naphtholthelein or mixtures thereof.
5. (Original) The device of claim 1 wherein the said indicator undergoes a yellow-to-blue, red-to-yellow or red-to-blue color change.
6. (Original) The device of claim 1 wherein said polymer is soluble in an organic solvent.
7. (Original) The device of claim 1 wherein said polymer is soluble in water or is water dispersible.
8. (Original) The device of claim 7 wherein said polymer is a homopolymer, or a copolymer or a mixture thereof.

9. (Currently Amended) The device of Claim 8 wherein said polymer is a polymer of styrene, acrylate, acrylic acid, acrylamide, vinyl acetate, vinyl alcohol, vinyl chloride, ~~styrene~~ or a mixture thereof.

10. (Original) The device of claim 9 wherein the polymer is an acrylate polymer.

11. (Original) The device of claim 6 wherein the polymer is cellulose nitrate or carboxymethylcellulose.

12. - 39. (Cancelled)

40. (Previously Presented) A process of using a device for monitoring sterilization of materials,

said device comprising

at least one layer of polymer, having incorporated therein

a) an indicator capable of undergoing at least one color change when subjected to a rise in pH,

b) an activator for said indicator, said activator having a monovalent cation, which, when contacted with ethylene oxide, undergoes a reaction wherein the product of said reaction causes a rise in pH said rise in pH causing said indicator to undergo said color change,

comprising the steps of

c) affixing the device to said materials or containers containing same

d) carrying out the process of sterilization including the step of introducing ethylene oxide and

e) observing the presence of a color change of said device.

41. (Previously Presented) A process of using a device for monitoring ethylene oxide, said device comprising

at least one layer of polymer, having incorporated therein

a) an indicator capable of undergoing at least one color change when subjected to a rise in pH,

b) an activator for said indicator, said activator having a monovalent cation, which, when contacted with ethylene oxide, undergoes a reaction wherein the product of said reaction causes a rise in pH said rise in pH causing said indicator to undergo said color change,

comprising the steps of

- c) exposing the device to ethylene oxide,
- d) observing the presence of color change in the device.

42. (Currently Amended) The process of claim 40 wherein the cation is selected from the group consisting of lithium, sodium, potassium, cesium, quaternary nitrogen, quaternary phosphorous phosphorus and quaternary sulfur.

43. (Previously Presented) The process of claim 40 wherein the anion is selected from the group consisting of bisulfite, bisulfate, carbonate, carbamate, carboxylate, cyanate, halide, nitrite, nitrate, phenolate, phosphate, sulfate, sulfide, sulfite, and thiocyanate.

44. (Previously Presented) The process of claim 41 wherein the anion is selected from the group consisting of bisulfite, bisulfate, carbonate, carbamate, carboxylate, cyanate, halide, nitrite, nitrate, phenolate, phosphate, sulfate, sulfide, sulfite, and thiocyanate.

45. (Currently Amended) The process of claim 41 wherein the cation is selected from the group consisting of lithium, sodium, potassium, cesium, quaternary nitrogen, quaternary phosphorous phosphorus and quaternary sulfur.